

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO:  ETHICON ELECTION WAVE CASES LISTED IN EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DEFENDANTS' MOTION TO EXCLUDE THE GENERAL CAUSATION EXPERT  
OPINIONS OF DR. KONSTANTIN WALMSLEY FOR THE ELECTION WAVE**

Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) move to exclude Dr. Walmsley's general causation opinions because they fail to satisfy the standard set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and as expressed by this Court in prior rulings. This motion applies to the Election Wave cases identified in Exhibit A attached hereto.

**Notice of Adoption**

In previous Waves, through his case-specific reports, Dr. Walmsley has offered certain general-causation opinions, which Plaintiffs have incorporated by reference into the cases identified in Ex. A in this Election Wave. Ethicon hereby adopts and incorporates by reference the *Daubert* motions filed against Dr. Walmsley on these issues for Ethicon Waves 1, 2, 3, 4, and 8. Dkts. 1998 (Wave 1 motion), 1999 & 2245 (Wave 1 memorandum in support and reply); Dkts. 2451 (Wave 2 motion), 2454 (Wave 2 memorandum in support); Dkts. 2823 (Wave 3 motion), 2824 & 3012 (Wave 3 memorandum in support and reply); Dkts. 3585 (Wave 4 motion), 3586 & 3835 (Wave 4 memorandum and reply); Dkt. 6879 (Wave 8 motion and

memorandum in support).<sup>1</sup> For the reasons expressed in these motions, Ethicon respectfully requests that the Court exclude Dr. Walmsley's testimony on these issues.

Motion to Exclude Dr. Walmsley's New Election Wave General-Causation Opinions

In addition to the general-causation opinions Dr. Walmsley has offered in certain case-specific reports in past Waves, in the following two Election Wave cases, Dr. Walmsley seeks to offer new general-causation opinions by incorporating them into his case-specific expert reports: Ex. B, Expert Report of Dr. Walmsley, *Harris v. Ethicon, Inc., et al.*, No. 2:12-cv-03246; Ex. C, Expert Report of Dr. Walmsley, *Ray v. Ethicon, Inc., et al.*, No. 2:12-cv-04475.

None of Dr. Walmsley's new opinions is supported by reliable methodology. Instead, within these case-specific reports, he offers summaries of his general causation opinions: he never explains them, and he never provides *any* scientific analysis, literature citation, or other support for his conclusions. Although Plaintiffs' expert disclosures in these cases refer generally to all of Dr. Walmsley's expert reports that have ever been served in this MDL (Ex. D & E), he has never submitted a separate "general report" in this litigation—in any Wave, for any product—nor does he attach or specifically cite these reports. Rather, he simply asserts two separate "general opinions" that are pure *ipse dixit* and should be excluded.

**First**, Dr. Walmsley opines that the TVT-O IFU "was not sufficient to enable informed consent from the patient." Walmsley Rpt. (Harris) at 4; Walmsley Rpt. (Ray) at 5. Use of phrases like "adequate" or "sufficient" is tantamount to employing legal terms of art, and this opinion should be limited. This Court has repeatedly held that experts may not provide opinion testimony that states a legal standard, uses a legal term of art, or draws a legal conclusion by

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<sup>1</sup> See also Dkt. 2652 (Wave 1 Memorandum Opinion and Order); Dkt. 3556 (Wave 2 Order Adopting Wave 1 Memorandum Opinion and Order); Dkt. 4215 (Wave 3 Order Adopting Wave 1 Memorandum Opinion and Order); Dkt. 6280 (Wave 4 Order Adopting Wave 1 Memorandum Opinion and Order).

applying law to the facts—e.g., “failed to adequately disclose,” “defective,” “not reasonably safe”,<sup>2</sup> or as in this case “insufficient.”

Furthermore, whether a label is adequate or “sufficient” to convey the risks of a product depends on an assessment of the common knowledge held by the intended users—here, pelvic floor surgeons. *See* Miss. Code Ann. § 11-1-63(c)(ii) (emphasis added) (in determining the adequacy of a prescription product’s warning, the “ordinary knowledge common to physician or other licensed professional who prescribes the drug, device or other product.”) And, whether informed consent is sufficient in any given case depends on the implanting surgeon’s actual knowledge and what that surgeon conveys to the patient. *See Smith v. Johnson & Johnson*, 2011 U.S. Dist. LEXIS 98719, at \*37 (S.D. Miss. Aug. 31, 2011) (where “the physician was aware of the possible risks involved in the use of the product but decided to [prescribe] it anyway, the adequacy of the warning is not a producing cause of the injury and the plaintiff’s recovery must be denied.”); La. Rev. Stat. § 9:2800.57(B)(2); *see also Duncan v. Louisiana Power & Light Co.*, 532 So.2d 968, 972 (La. App., 5th Cir. 1988) (“There is no duty to warn a sophisticated user of dangers of which he may be presumed to know through his familiarity with the product.”); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. Tex. 1999) (“If the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury.”).

Dr. Walmsley has made no effort to apply these standards to his assessment of whether the TVT-O IFU was adequate or whether informed consent was possible. *See* Walmsley Rpt. (Harris) at 5-6; Walmsley Rpt. (Ray) at 4-5. Dr. Walmsley’s resulting opinion is therefore

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<sup>2</sup> See, e.g., *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at \*4 (S.D.W. Va. Aug. 30, 2016); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*3 (S.D.W. Va. Apr. 24, 2015); *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at \*21 (S.D.W. Va. Jan. 15, 2014).

confusing and unhelpful. He does not apply the correct legal standards, yet purports to reach legal conclusions that will simply mislead the jury. Incredibly, Dr. Walmsley offers absolutely no scientific support or analysis for these opinions, other than his own beliefs and “experiences”. His opinions regarding the sufficiency or adequacy of the TVT-O IFU should be excluded.

**Second**, Dr. Walmsley’s opinion that “safer alternative designs and procedures existed . . . that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy” is unreliable and irrelevant. As an initial point, Dr. Walmsley does not identify any particular alternative design that would have been safer or equally effective. He cites no literature, nor any scientific evidence of any kind, in support of his opinion. For this reason alone, his opinion regarding a vague “alternative design” should be excluded.

Additionally, his opinions regarding alternative procedures are irrelevant and unhelpful to the jury. As this Court recognized in another case involving an Ethicon vaginal mesh implant, *Mullins v. Johnson & Johnson*, No. 2:12-cv-02952, 2017 WL 711766 (S.D.W. Va. Feb. 23, 2017) (applying W.Va. law), “an alternative, feasible design must be examined in the context of products—not surgeries or procedures.” *Id.* at \*2. Following the Fourth Circuit’s decision in *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999), which rejected evidence of surgical alternatives to a spinal fixation device, this Court explained:

Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been performed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible *design* for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence (“SUI”); other surgeries or procedures do not inform the jury on *how* the TVT’s design could have feasibly been made safer to eliminate the risks that caused the plaintiffs’ injuries.

*Id.* (citing *Talley*, 179 F.3d at 162; W. Va. P.J.I. § 411).<sup>3</sup>

Louisiana law governs the design defect claims in the *Harris* case, while Mississippi law governs the claims in the *Ray* case. Both states' law resembles West Virginia law in that they require proof concerning a defect in the *design* of the relevant product. See La. Rev. Stat. § 9:2800.56; *Reeves v. AcroMed Corp.*, 44 F.3d 300, 308 (5th Cir.1995); *Williams v. Bennett*, 921 So. 2d 1269, 1275 (Miss. 2006) (discussing Restatement (Third) of Torts: Product Liability § 2 (1998)); Miss. Code Ann. § 11-1-63(f)(ii); *Elliott v. El Paso Corp.*, 2015 WL 515579, \*6 (Miss. Sept. 3, 2015). As was the case in *Mullins*, alternative surgical procedures distract from the requisite analysis because they say nothing about the availability of a technically feasible alternative product design or formulation. Because the relevant states' law for design defect claims aligns with their West Virginia counterpart, *Mullins* is applicable here. Dr. Walmsley's safer-alternative procedures opinion should therefore be excluded in its entirety because an alternative method of treatment is not an alternative design that can support Plaintiffs' design defect claims.

This Court has routinely excluded opinions where an expert, as here, fails to provide sufficient scientific support for such generalized causation opinions. "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively

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<sup>3</sup> *Mullins* and *Talley* are not outliers. Numerous courts around the country, applying the substantive law of different states, have similarly found surgical alternatives irrelevant to design defect claims. See, e.g., *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255–56 (5th Cir. 1999); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at \*2 (D. Nev. July 22, 2013); *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358, at \*3 (E.D. La. Mar. 30, 2000); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95–8646, 1999 WL 1132313, at \*4 (S.D. Fla. Apr. 9, 1999); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999); *Hosford v. BRK Brands, Inc.*, Nos. 1140899 & 1140901, 2016 WL 4417256, at \*8 (Ala. Aug. 19, 2016). Simply put, "alternative methods of treatment are *not* alternative designs." *Hornbeck v. Danek Med., Inc.*, No. 99-30966, 2000 WL 1028981, at \*1 (5th Cir. July 5, 2000) (emphasis in original).

[chooses] his support from the scientific landscape.” *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014) (GOODWIN, J.), *as amended* (Oct. 29, 2014) (citing *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y.2005)). “[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.” *Id.* (citing, *inter alia*, *Rezulin*, 369 F. Supp. 2d at 425); *Mathison v. Boston Sci. Corp.*, 2015 WL 2124991, \*7-8 (S.D.W. Va. 2015)(excluding opinions of Dr. Margolis regarding failure rates where he failed to explain why he disagreed with contrary studies and discounted scientific studies and instead gave patients “the benefit of the doubt” as to complication rates). Here, because Dr. Walmsley has failed to support his general causation opinions *at all*, much less consider or explain contrary studies, they should be excluded in their entirety.

Dr. Walmsley’s general-causation opinions lack reliability and relevance and should be excluded in their entirety.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage  
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